

SEP 30 1998

SYBRON

DENTAL SPECIALTIES, INC.

K982459

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: July 1998

Device Name:

- Trade Name - TempFil F - 2
- Common Name - Temporary Dental Restorative Material
- Classification Name - Temporary Crown and Bridge Resin, per 21 CFR § 872.3770

Devices for Which Substantial Equivalence is Claimed:

- Vivadent, *Fermit-N*
- Cosmedent, Inc., *E-Z TEMP*

Device Description:

The device is a visible light-cured, single component temporary filling material. It is specifically designed for temporary inlays and onlays. TempFil F - 2 has a permanent elastic phase which allows for easy removal even in the presence of preparation undercuts.

Intended Use of the Device:

The intended use of TempFil F - 2 is for temporary filling of inlay and onlay preparations, implant screw access openings and for the emergency replacement of lost fillings.

Substantial Equivalence:

TempFil F - 2 is substantially equivalent to several other legally marketed devices in the United States. The temporary dental restoratives marketed by Vivadent and Cosmedent, Inc. function in a manner similar to and are intended for the same use as the product manufactured by Kerr Dental Materials Center.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 1998

Ms. Colleen Boswell
Senior Regulatory Affairs Specialist
Sybron Dental Specialties, Incorporated
1717 W. Collins Avenue
Orange, California 92867

Re: K982459
Trade Name: TempFil F - 2
Regulatory Class: II
Product Code: EBU
Dated: July 13, 1998
Received: July 15, 1998

Dear Ms. Boswell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.


If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Boswell

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


B Timothy A. Ulatowski

Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

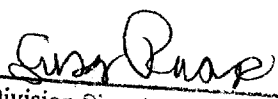
Section I - Indications for Use

510(k) Number: _____

Device Name: TempFil F - 2

Indications for Use:

TempFil F - 2 is a ~~light-cured~~ single component ~~temporary~~ filling material intended to be used for inlay and onlay preparations, ~~implant screw access openings and~~ for the emergency replacement of lost fillings.



(Division Sign-off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K9F2459